

8/14



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,544	05/04/2001	Ronald A. Faris	21486-024 NATL	2853

7590 04/21/2004
Ingrid A Beattie
Mintz Levin Cohn Ferris Glovsky & Popeo
One Financial Center
Boston, MA 02111

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,544

Applicant(s)

FARIS, RONALD A.

Examiner

Joseph T. Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41,50-61 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41,50-61 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 12, 2004 has been entered.

DETAILED ACTION

This application is a 371 national stage filing of PCT/US99/15625, filed July 8, 1999, which claims benefit of 09/113,774, file July 10, 1998, now US Patent 6,129,911.

Applicant's amendment filed January 12, 2004 has been received and entered. Claims 49, 62-64 have been canceled. Claims 35, 36, 39, 40 and 58-61 have been amended. Claims 65-67 have been added. Claims 35-41, 50-61 and 65-67 are pending.

Election/Restriction

Applicant's election without traverse of group III, claims 35-41, drawn to a method of obtaining isolated liver stem cells, in Paper No. 6 was acknowledged. Newly added claims 65-67 are dependent claims depending directly or indirectly to claim 35 and are encompassed by the elected invention. Accordingly, claims 35-41, 50-61 and 65-67 are currently under examination.

Oath/Declaration

The declaration filed January 12, 2004 is in compliance with 37 CFR 1.67(a).

The newly submitted declaration has obviated the basis of the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-41, 50-61 and 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 is unclear in the recitation of “wherein said population of clusters is enriched for liver stem cells compared to said liver tissue” because the composition obtained from a liver can only contain the stem cells that were originally present in the liver. It is unclear how practicing the method would result in more stem cells than previously present in the liver from which they were obtained. Upon review of the specification it does not appear that the method results in the formation of new liver stem cells, only the isolation of existing stem cells in this case as at least doublets associated with hepatocytes.

Claim 36 recites the limitation “the step” and “wherein said step of enriching” in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. More specifically, claim 35 and 36 comprise multiple steps, and it is unclear to what step of enriching is be referred. More clearly indicating that claims 36 encompasses an additional step or more clearly indicating how the step of claim 36 is affected would obviate the basis of the rejection.

Claim 38 is unclear in the recitation and limitation that the stem cell and hepatocyte are derived from the canal of Hering, because it is unclear how this further limits the scope of the claims. It is unclear if this represents a specific population of clusters or only an indication of where the clusters reside in the liver. If it is the latter case, this would not limit the claims because it is an inherent property of the cluster being isolated. If the specification supports such a limitation these claims may be amended to be used as an active step in the isolation.

Claims 65 and 67 are unclear in the recitation and limitation that the stem cell and hepatocyte are joined by desmosomal junction, because it is unclear how this further limits the scope of the claims. Similar to as discussed above, it is unclear if this represents a specific population of clusters, or only a characterization of the cells in the cluster. If it is the latter case, this would not limit the claims because it is an inherent property of the cluster being isolated. If the specification supports such a limitation these claims may be amended to be used as an active step in the isolation (similar to claim 39).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-41, 49-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35-44 of U.S. Patent No. 6,129,911 ('911) is withdrawn.

The filing of the terminal disclaimer over '911 has obviated the basis of the rejection.

Conclusion

No claim is allowed.

As noted in the previous office action, the claims are free of the art of record because the art fails to teach or suggest the isolation of cell clusters of 2-5 cells from the liver wherein the cells comprise the OV6 marker and do not comprise the OC2 marker. However, the claims are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

A handwritten signature in cursive script that reads "Joe Voitach".

AV1632